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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,859	10/23/2003	Charmaine K. Harris	P11285.00 US	6734

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EXAMINER

JACKSON, BRYAN M

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/691,859	Applicant(s) HARRIS, CHARMAINE K.	
	Examiner Bryan M. Jackson	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/23/03 9/2/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The Information disclosure statement (IDS) submitted on 10/23/2003 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5, 7, 9-14, 17, 19, 21-26, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson (6895283) in view of Lekholm (5042463).

Erickson discloses a lead (fig 1, 10) including a plurality of electrically conductive electrodes (fig 1, 20) arranged within a flat paddle-like structure (fig 1, 16), wherein the paddle-like structure is formed of a medical grade polyurethane material (col 5, ln 13-15).

Erickson discloses the claimed invention except for the radio-opaque material. Lekholm teaches that it is known to use a radio-opaque marker (fig 1, 16) on a defibrillation electrode in the analogous art of implanted electrodes in

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order to externally view the orientation of an implanted electrode (see col 3, In 23-27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify flat paddle with a plurality of electrodes, as taught by Erickson, with a radio-opaque marker on an implanted electrode, as taught by Lekholm, in order to provide a means for externally viewing the orientation of an implanted electrode.

Erickson and Lekholm disclose the claimed invention but do not disclose expressly the radio-opaque material arranged, dispersed, or dispersed uniformly in an asymmetric manner with respect to the width of the paddle (claim 10-12, 22-24, and 26-28). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the fluoroscopically viewable material of radio-opaque material with a plurality of spaced apart points along a distal end with respect to a medical lead, as taught by Erickson and Lekholm, with the radio-opaque material arranged, dispersed, or dispersed uniformly in a asymmetric manner with respect to the width of the paddle, because Applicant has not disclosed that radio-opaque material arranged, dispersed, or dispersed uniformly in a asymmetric manner with respect to the width of the paddle, provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the fluoroscopically viewable material of radio-opaque material with a plurality of spaced apart points along a distal end with respect to a medical lead, as taught by Erickson and Lekholm, because it provides the orientation and direction of the implanted medical lead,

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and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Erickson and Lekholm.

Therefore, it would have been an obvious matter of design choice to modify Erickson and Lekholm to obtain the invention as specified in the claim(s).

Claims 3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson and Lekholm as applied to claim 1 above, and further in view of Baudino (6185463).

Erickson and Lekholm disclose the claimed invention except for the recessed electrodes relative to a major surface. Baudino teaches that it is known to use electrodes located along a lead body that are recessed from the outer surface of the lead body (abstract) to prevent contact between electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plurality of electrodes, as taught by Erickson and Lekholm, with electrodes located along a lead body that are recessed from the outer surface of the lead body, as taught by Baudino, in order to eliminate contact between electrodes via recessed electrodes.

Claims 4, 16, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson and Lekholm as applied to claim 1 above, and further in view of Duncan (20030139782).

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Erickson and Lekholm disclose the claimed invention except for the orientation marker coded to identify a model or serial number. Duncan teaches that it is known to use radio-opaque identification markings to identify an implant by model number (pg 7, para 0145) in the analogous art of implantable muscle stimulators. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fluoroscopically viewable material of radio-opaque material with respect to a medical lead, as taught by Erickson and Lekholm, with the radio-opaque identification of a model number, as taught by Duncan, in order to enable identification of the lead by model number.

Claims 6, 8, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson and Lekholm as applied to claim 1 and 13 above, and further in view of Alt et al. (5876408).

Erickson and Lekholm disclose the claimed invention except for the use of platinum as the radio-opaque material. Alt et al. teaches that it is known to use platinum including alloys to increase the visibility of an object within a biological organism under fluoroscopy (col 3, ln 47-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made, absent any teaching of criticality or unexpected result, to have substituted any known radio-opaque material for those taught in the modified Erickson device, such as those taught by Alt et al., as a mere substitution of known functional equivalents.

Conclusion

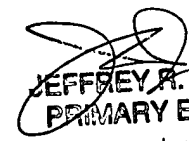
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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cross (20020111661) discloses a multiple electrode lead body for spinal cord stimulation. Gillies (6272370) discloses a MR-visible medical device for neurological interventions using nonlinear magnetic stereotaxis and a method imaging.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryan M. Jackson whose telephone number is 571-272-7335. The examiner can normally be reached on Monday through Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JEFFREY R. JASTRZAB
PRIMARY EXAMINER
2/15/06